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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,140	08/08/2001	Preeti Lal	PF-0512-1 DIV	3400

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INCYTE GENOMICS, INC.  
PATENT DEPARTMENT  
3160 Porter Drive  
Palo Alto, CA 94304

EXAMINER

HELMS, LARRY RONALD

ART UNIT PAPER NUMBER

1642

DATE MAILED: 04/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/925,140

Applicant(s)

LAL ET AL.

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18, 27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-18, 27-28 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) ____.   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other:  |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1, 2, 16, and 17, drawn to a polypeptide and compositions comprising such, classified in class 530, subclass 350.
  - II. Claims 3-7, 9, 11, and 12, drawn to polynucleotides, host cells, method of expressing, classified in class 536, subclass 23.1, for example.
  - III. Claim 8, drawn to a transgenic organism, classified in class 800 subclass 8.
  - IV. Claim 10, drawn to an antibody, classified in class 530, subclass 387.1.
  - V. Claims 13-14, drawn to a method of detecting a polynucleotide by hybridization, classified in class 435, subclass 6.
  - VI. Claim 15, drawn to a method of detecting a polynucleotide by PCR amplification, classified in class 435, subclass 91.2.
  - VII. Claim 18, drawn to a method of treatment of a disease by administering a polypeptide, classified in class 514, subclass 2.
  - VIII. Claim 27, drawn to a method of screening a compound for effectiveness in altering expression, classified in class 435, subclass 6, for example.
  - IX. Claim 28, drawn to a method of assessing toxicity of a compound by detecting a hybridization complex, classified in class 435 subclass 6, for example.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-IV represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. The polynucleic acid of Group II, the protein product of Group I, the antibody of Group IV, and the transgenic organism of Group III are all structurally and chemically different from each other. The polynucleotide is made by nucleic acid synthesis, while the polypeptide is made by translation of mRNA, the antibody is raised by immunization and transgenic organism is made by reproductive techniques. Furthermore, the polynucleotide can be used for hybridization screening, the polypeptide can be used for methods of treatment, the antibody can be used to immunopurify the polypeptide and the transgenic organism can be used for models of treatment or disease states, for example. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions I-IV are patentably distinct.

The methods of Inventions V-IX differ in the method objectives, method steps and parameters and in the reagents used. Invention V recites a method of detecting a polynucleotide by hybridization; Invention VI recites a method of detecting a polynucleotide by PCR amplification; Invention VII recites to a method of treatment of a disease by administering a polypeptide; Invention VIII recite a method of screening a compound for effectiveness in altering expression and Invention IX recites a method of assessing toxicity of a compound by detecting a hybridization complex. The examination of all groups would require different searches in the U.S. PATENT shoes

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and the scientific literature and would require the consideration of different patentability issues. Thus Inventions V-IX are separate and distinct in having different method objectives, method steps and parameters and in the reagents used and are patentably distinct.

Inventions II and V, VI, VIII, and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of Group II can be used in any one of the materially different methods of Groups V, VI, VIII, or IX.

Inventions I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group I can be used in a materially different method such as an immunogen to prepare antibodies in addition to the materially different method of Group VII.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classifications, restriction for examination purposes as indicated is proper.

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4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D., whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

6. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,  
Larry R. Helms Ph.D.  
703-306-5879

